UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,364	09/06/2000	Alice C. Martino	6107.N CN2	3730

7590 12/19/2001

Pharmacia & Upjohn Company
Global Intellectual Property
301 Henrietta Street
Kalamazoo, MI 49001

EXAMINER	
SHARAREH, SHAHNAM J	
ART UNIT	PAPER NUMBER
1619	

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/656,364	MARTINO ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1619	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,26 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,26 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary amendment filed on September 6, 2000 has been entered. Claims 1-24, 26 and 30 are pending in this application.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-7, 9-10, 12-13, 18, 20-21, 24, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Weintraub et al US Patent 4,013,785.

The instant claims are directed to a non-sustained release, non-chewable pharmaceutical tablet form comprising a rapidly precipitating drug, microcrystalline cellulose, and at least one binder in an amount of from about 2 to about 25% or a superdisintegrant in an amount from about 6 to about 40%.

Weintraub discloses a fast release tablet comprising a rapidly precipitating drug such as n-acetyl-paminophenol, diphenhydramine, chorpheniramine, phenylepherine..., microcrystalline cellulose, a binder, a flow agent such as colloidal silicon dioxides and a

superdisintegrant such as sodium starch glycolate (see col 2, lines 1-35; col 7 lines 34-67, col 8 lines 14-39, claim 1, 9, 13). Examples 4 and 5 of Weintraub anticipates the instantly claimed amounts of each ingredient (see col 8, lines 14-39). Thus, Weintraub's compositions meet the limitations set forth in the instant claims.

Claims 1-7, 9-10, 12-13, 17-24, 26, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Akkerboom et al US Patent 5,211,958.

Akkerboom discloses tablet compositions comprising a rapidly precipitating drug such as tetracycline or oxytetracycline or doxycycline, microcrystalline cellulose, Low substituted hyroxypropyl cellulose (the instant superdisintergrant), hydroxypropyl methylcellulose (HPMC), lactose, and colloidal silica (abstract; col 4, lines 34-45; col 2, lines 65-67; col 2, lines 36-57). The amounts of above ingredients falls with in the same range as the instantly claimed amounts (see examples 1, 3; col 5, lines 10-12). Akkerboom also teaches the use of other binding substances such as PVP (col 3, lines 29-30). Accordingly, Akkerboom meets the limitations of the instant claims.

Claims 1-3, 6-7, 9-10, 12-13, 16-24, 26, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al US Patent 5,256,699.

Murphy discloses diclofenac tablets comprising diclofenac, microcrystalline cellulose, lactose, sodium croscarmellose, lactose, HMPC, magnesium stearate, and colloidal silicon dioxide (see examples in col 2-3; col 4, line 45; col 1, line 67). The examples of Murphy teaches diclofenac concentrations in amounts of about 17% wt, microcrystalline cellulose in amounts of about 37%, lactose in amounts of about 37%, sodium croscarmellose in amount of about 8%, HPMC in amounts of about 0.8%, a

lubricant such as magnesium stearate in amounts of about 2% and finally a flow agent such as colloidal silicon dioxide in amounts of about 2%). Murphy states that diclofenac has a very low solubility (col 1, lines28-29), thus it is considered as a rapidly precipitating drug. Murphy also discloses manufacturing his tablets by so-called direct compression using suitable grades of ingredients (see col. 2, lines 8-13). Accordingly, Murphy anticipates the limitations of the instant claims.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4-5, 8, 11, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy et al US Patent 5,256,699 in view of Remington: The

Science and Practice of Pharmacy 1995 (pp.1395, 1397, 1398, 1411, 1617-1618) (Remington)

The teachings of Murphy are discussed above. Murphy fails to teach the instantly claimed percentages of binders, the use of PVP, and the various types of lactose in his formulations.

Remington provides that HPMC, microcrystalline cellulose, and PVP (polyvinylpyrrolidone) are either used as a thickening agent or a binder in the field of formulation pharmacy, therefore HPMC and PVP are art recognized equivalents (see p. 1397-1398, 1617-1618 under title binder). Remington also sets forth that lactose exists in various forms, including a monohydrate form, and all various forms are used as diluents in the field of medicine and pharmacy (see pp. 1411). Accordingly, Examiner views all various forms of lactose to be art recognized equivalents in the field of formulation pharmacy.

Although Murphy does not use various forms of binders or lactose, he suggests that for direct compression process suitable diluents and grades thereof may be selected as recognized by the skilled artisan (see col 2, lines 4-12). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute binders or lactose of Murphy with other suitable art recognized equivalents, namely PVP for HPMC and various forms of lactose, because the ordinary skill in the art would have had a reasonable expectation to observe similar activity.

Furthermore, differences in concentration will not support patentability of subject matter encompassed by the prior art, unless there is evidence indicating such

concentrations is critical (see MPEP 2144.05 II). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the concentrations of Murphy's binder by routine experimentation to achieve desirable pharmacokinetic properties of a therapeutic agent of choice

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Shahnam Sharareh, PharmD
Patent Examiner, Art Unit 1619

ss
December 15, 2001